REMARKS/ARGUMENTS

Claims 1 – 19 are pending in the application.

New claims 17 – 19 have been added to address the feature that Applicants' probe is adapted to be self-applied without the use of a tool.

CLAIM REJECTIONS – 35 USC § 112

To demonstrate that the "non-implanted" language used in Applicants' claims is the terminology used and known by those of ordinary skill in the art, Applicants' submitted a number of FDA definitions. The Examiner, on page 8 of the present Office Action, has stated that the FDA and the USPTO are different government agencies, and that metes and bounds of terminology required by one of those agencies is not necessarily applicable to the other. Applicants respectfully disagree with regard to the present situation. In particular, Applicants are addressing the meaning of terminology to and use by those of ordinary skill in the art in the relevant field.

The Examiner's reluctance to accept the standard language of the industry is not understood. It is certainly not a matter of the FDA dictating anything to the USPTO, but rather of regulation of those of skill in the art in the medical field. That the FDA is the required regulating agency with regard to the subject device of the present application can be found in Title 21 of the Code of Federal Regulations, where in Chapter 1 (see Exhibit 1) it is stated that medical devices are regulated by the Food and Drug Administration (FDA). This is primarily due to the fact that the FDA regulates devices to assure their safety and effectiveness. That the device of the present application is a medical device is clear from the paragraph in Exhibit 1 entitled WHAT IS A MEDICAL DEVICE.

Further with respect to the Examiner's concern about the metes and bounds of terminology, he has referred to the first sentence of the third paragraph of Applicants' FDA approval letter (see Exhibit 2), which indicates that Applicants may still need to comply with the requirements of other federal agencies. Applicants respectfully submit that this paragraph has nothing to do with the FDA's control over terminology that is applicable to those practicing in the medical field, and therefore defines the metes and bounds of terminology that would be understood by those of skill in the art. Support for Applicants' position can be found at the end of the first paragraph and the beginning of the second paragraph of MPEP section 2111, where it is stated that the PTO applies to verbiage of claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art; it is furthermore stated that the broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach. Therefore, those of ordinary skill in the art use the terminology that is common in their industry and that moreover is used by their regulating agency, namely the FDA; those of ordinary skill in the art would not look to Merriam Webster's Collegiate Dictionary for a definition of relevant terms, especially since this is not even a technical dictionary. In this respect, the Examiner's attention is directed to the July 2005 CAFC case of Phillips v. AWH Corp., No. 03-1269,7/12/05, in which it is stated that although claims are generally given their ordinary meaning, this refers to the ordinary meaning to a person of skill in the art at the time the application was filed. See also section II of MPEP section 2111.01.

On page 8 of the Office Action, the Examiner has also stated that Applicants' usage of the term "non-implanted" is not consistent with the usage of the FDA.

Applicants respectfully disagree. In support of Applicants' consistent usage of the terminology, Applicants again refer to the FDA approval letter that is Exhibit 2. At the very beginning, in the heading, the FDA indicates that the regulation name is specifically non-implanted electrical continence device. Reference is also made in this heading to the definition code or regulation number in 21 CFR § 876.5320, which can be found in subpart F of Exhibit 3. As further evidence that "non-implantable" (i.e. a derivative of non-implanted) is a term of art in the relevant industry, the Examiner's attention is directed to Exhibit 4, which is operating instructions for coverage of non-implantable pelvic floor electrical stimulators, as issued by the Department of Health and Human Services.

Although in the last paragraph of page 8 of the Office Action, the Examiner indicates that "one cannot be certain of the scope of this negative limitation" (namely non-implanted), Applicants respectfully submit that one of ordinary skill in the art certainly is knowledgeable of the scope of this terminology. That this is the case is furthermore made clear by paragraph 5 of the enclosed revised declaration of Dr. Christopher J. Jayne (see Exhibit 5).

The statement also in the last paragraph on page 8 of the Office Action that even an "implant" could be considered "non-implanted" before such device is surgically inserted is certainly contrary to the usage characterization of such an implant device. One of ordinary skill in the art certainly understands that when an implant device is sitting on the shelf prior to use it is not implanted; however, such device is certainly "adapted to be" implanted and this structural attribute of such a device will be discussed in greater detail below with regard to the Guice reference.

In view of the foregoing detailed comments as well as the attached Exhibits, Applicants respectfully submit that the "non-implanted" terminology is in fact the correct and definite term of art in the pertinent field, and those of ordinary skill in the art are quite clear about the meaning thereof. Applicants therefore respectfully request that the Examiner withdraw his rejections under 35 USC § 112.

CLAIM REJECTIONS – 35 USC § 102 and 103

The Examiner has rejected, among others, claims 1, 14 and 16 as being anticipated by Blythe.

Applicants' claims 1, 14 and 16 require, among other features, a separate combination probe, transceiver and power source that is provided with 2-way wireless communication means for transmitting information and for receiving control and programming signals; also required is a separate unit in the form of a combination controller and transceiver that is provided with wireless means for sending signals to the probe and for receiving signals therefrom.

The majority of the embodiments disclosed by the Blythe reference require a physical control cable 76 that extends from the computer 75 to the interface port 72 on the probe 10. With regard to the wireless embodiment referenced by the Examiner in column 8, lines 31 – 34, this refers to the embodiment of Fig. 5, and certainly provides no teaching that would enable one of skill in the art to construct a probe having 2-way wireless communication means for transmitting information that is transduced and for receiving control and programming signals, all as required by Applicants' claims. Details of Blythe's wireless embodiment illustrated in Fig. 5 can be found in the following paragraph of column 8, lines 35 – 55. As stated in the previous paragraph in line 24, the modified probe of this embodiment is "for use in

veterinary applications". In particular, where no computer interface port 72 is used, the probe is provided with only a transponder signal receiver 92 that is adapted to receive an interrogating signal from an external transponder signal transmitter 94 on the collar 96. Thus, this embodiment provides only a transponder, which as defined in "The Illustrated Dictionary of Electronics" is a combination transmitter-transceiver that automatically transmits an identification signal when it receives an interrogating signal. The "responder" portion of the acronym refers to the transmitting section of the transponder (pertinent pages of the dictionary are attached as Exhibit 7). Thus, the wireless embodiment of Blythe provides neither a combination probe, transceiver and power source, nor the combination controller and transceiver, both as required by Applicants' claims. In contrast to Applicants' system and method, the Blythe device of Fig. 5 thereof functions merely to track the location of a subject animal (see column 8, lines 43 – 48). Thus, with the Blythe device there is at best a one-way tracking signal sent to the external collar 96, which as indicated above is not a combination controller and transceiver. Nor can control signals be received by the transponder signal receiver 92 of the probe 10 of Blythe. It is furthermore indicated in column 8, lines 54 and 55, that any "sensed" data is merely stored. Blythe's wireless embodiment in no way provides the 2-way wireless signal feedback loop required by Applicants' claims.

With regard to the Examiner's statement that the Blythe probe is a sealed unit, Applicants respectfully disagree. First of all, the Blythe probe is provided with the interface port 72. Thus, the end portion of the probe must be "maintained external to the patient" (column 7, lines 40 and 41), both to allow connection of the control cable 76, and to prevent fluids from entering this open or unsealed portion of the probe.

As further support for the unsealed nature of the Blythe unit, the Examiner's attention is respectfully directed to column 5, lines 32 – 40, where reference is made to the collection of fluids in the channel 40, and to the reference in column 7, lines 51 and 52, to the complete emersion of the sensors into the fluids that flow into the channel 40.

With regard to the Examiner's rejection of claims 8 – 10 over Blythe in view of Eini, reference is made to Applicants' foregoing comments, which are dispositive of the Blythe reference.

In view of the foregoing discussion, it is respectfully submitted that Blythe can neither anticipate any of Applicants' claims, since it does not teach every element of the claim in as complete detail as is contained in the claim (MPEP section 2131), nor can it make any claim obvious, since it does not teach or suggest all of Applicants' claim limitations (MPEP sections 2116.01 and 2143.03). Thus, it is respectfully requested that the Examiner withdraw his rejection of claims over the Blythe reference.

The Examiner continues to reject, among others, claim 1 as being anticipated by Guice. At issue are:

a) Whether or not the probe of Guice can be considered to be capable of being self-applied by a human subject into the human vagina, as required by Applicants' claim 1; and

b) Whether or not the probe of Guice could be considered to be "non-implanted", again as required by Applicants' claim 1.

With regard to issue a), the Examiner indicates that the language of Applicants' claim 1, namely "is adapted to be self-applied by a human subject into

the human vagina" is a recitation of the "intended use", and is not a structural difference. Applicants respectfully disagree, as will be discussed in greater detail subsequently. In particular, the "adapted to be self-applied" language is not merely an "intended use", but is a structural limitation that is a significant distinguishing feature between Applicants' system and the device of Guice.

In this regard, the Examiner's discussion regarding 35 USC § 112 on page 9 of the Office Action is not understood. In particular, 35 USC § 112 requires that a claim distinctly claim the subject matter regarded as the invention. MPEP section 2173 is provided to guide the claim drafting procedure, and is therefore very pertinent to the present discussion, since it helps in interpreting and understanding the requirements of 35 USC § 112. As a matter of fact, MPEP section 2173.01 states that "Applicant may use functional language, alternative expressions, negative limitations, or any style of expression or format of claim which makes clear the boundaries of the subject matter for which protection is sought".

As stated above, the "adapted to be self-applied by a human subject" language in Applicants' claim 1 is a structural limitation, and if the Guice probe does not provide this limitation for the probe, it cannot anticipate Applicants' claim, pursuant to MPEP section 2131. In support of the conclusion that Applicants' claim language that the probe is "adapted to be self-applied by a human subject" is in fact a structural feature, the Examiner's attention is respectfully directed to the very last paragraph of MPEP section 2173.05(g). Cited here is a CCPA case that held that the language "adapted to be positioned" served to precisely define present structural attributes of claim features. The Examiner's attention is also directed to the 1990 case of the Federal Circuit, Pac-Tec, Inc v. Amerace Corp (903 F.2d 796), cert

denied, where the court held that in determining whether a claim is anticipated, it is improper to disregard limitations that include "adapted to", with such language being held to constitute structural limitations. In citing an earlier case, the court furthermore affirmed that "functional language, in cases like the present, cannot be disregarded".

As stated above, if in order to anticipate Applicants' claim 1 the Guice probe must be capable of being self-applied by a human subject into the human vagina, then if the Guice probe is not so capable, it cannot anticipate Applicants' claim 1. In support of the structural distinction vis-a-vis Applicants' claim 1, namely that the Guice probe is clearly not "adapted to be self-applied by a human subject into the human vagina", Applicants have submitted the revised declarations of Dr. Jayne (Exhibit 5) and Dr. Wharton (Exhibit 8). In particular, as stated by Dr. Jayne in paragraph 6 of his declaration, whereas the Guice probe requires a tool, such as pliers, in order to install and remove the device from an animal, the device of the present application is defined to be "self-applied" by a human subject, "which to one of ordinary skill in the art is clearly understood to mean without the use of a tool, such as the pliers required by Guice". Dr. Jayne further indicates in the last sentence of paragraph 8 of his declaration "that to assert that a device made for a cow's vagina, or ear or any other cavity, would be capable of being inserted into a human vagina is simply not a reasonable interpretation to one of ordinary skill in this art". Similarly, Dr. Wharton, in referring to the device of Guice, states in the last sentence of paragraph 3 of his declaration that obviously "such a device is unacceptable and inappropriate for the human vagina, and in particular could not be self-applied or self-inserted by a human subject" (emphasis added). Therefore,

Guice does not teach all of Applicants' structural limitations, so that pursuant to MPEP section 2131 it is not a valid reference.

Furthermore, although the Examiner states at the bottom of page 10 of the Office Action that the FDA and the USPTO are different government agencies, and that definitions accepted by one of those agencies are not necessarily applicable to the other, such definitions are certainly pertinent to those skilled in the art, and as indicated above, MPEP section 2111 requires that the USPTO apply the meaning of words as they would be understood by one of ordinary skill in the art.

With regard to issue b), the definition of "non-implanted" as clearly understood by those of ordinary skill in the art has been previously dealt with. Furthermore, the FDA definition of implant (21 CFR 812.3(d), Exhibit 6) cannot be "loosely interpreted" to consider probes before they are inserted into a body as being "non-implanted", since this definition "means a device...intended to [comparable to "adapted to"] remain there for a period of thirty days or more". Since Guice clearly intends his probe to remain in place for at least thirty days (actually at least ninety days, as indicated in paragraph [0010]), Guice provides a structural limitation, namely that by definition his probe is an implant, that is exactly opposite of Applicants' "non-implanted" structural limitation in claim 1. This also explains why Guice consistently, and correctly, uses the term "implant" to describe his device.

Further support for the conclusion that the Guice probe is adapted to be implanted, in contrast to Applicants' "non-implanted" limitation, can be found in the aforementioned revised declarations of Dr. Jayne and Dr. Wharton. Dr. Jayne first indicates in paragraph 4 of his declaration that one of ordinary skill in the art would not look to Guice for any teaching with respect to how to configure a device that is

intended to be inserted in a non-implanted manner, which he factually supports not only from his in-depth study of Guice (which already by its title is clearly limited to applications for animals, which to Dr. Jayne is very understandable given the significant anatomical differences between the vaginas of animals and those of humans), but also from the FDA standards, regulations and safety concerns implemented by the definition of "implants". In paragraph 6, Dr. Jayne describes how the Guice probe is to be kept in place, and in paragraph 7 he clearly states that the device of the present application is not an implant, whereas in contrast the device of Guide would be considered by one of ordinary skill in the art to be an implant. Dr. Jayne then discusses how Guice himself stresses that his device is a true implant, with Dr. Jayne stating that the reason that the Guice device is an implant is in large part due to the differences in the anatomy of humans and animals, which therefore requires that the device of Guice be implanted so that it will be retained in the animal that is being monitored, and not be expelled during urination. Dr. Jayne's conclusions (paragraphs 3 and 8) are that one of ordinary skill in the art would not consider the Guice reference when trying to provide a system for transducing vaginal conditions, etc. in humans, and that the Guice device is entirely unsuitable for human vaginal use, so that one of ordinary skill in the art would not consider the Guice (implant) device for any teaching or suggestion with regard to a non-implanted device.

Similarly, Dr. Wharton, in paragraph 3 of his declaration, explicitly states that the Guice device is an implant. Dr. Wharton's conclusions, as stated in paragraph 2, the end of paragraph 4, and in paragraph 5, are that he would give no consideration to the Guice patent, that the device of the present application is in no way

comparable to the Guice implant device, that the Guice implant device is in no way appropriate or acceptable for use in the human vagina, and that individuals of ordinary skill in the art developing medical devices for temporary placement, i.e. application or insertion, within the human vagina would not consider the Guice reference.

Starting at the bottom of page 11 of the Office Action, the Examiner has attacked Dr. Jayne's and Dr. Wharton's previously submitted declarations as being inadequate. These are two highly qualified individuals. In particular, both are graduate physicians of accredited medical schools, are skilled in the art of medicine and, in particular, are specialists in the field of human obstetrics and gynecology. Further, both physicians are Board Certified by the Ameican Board of Obstetrics and Gynecology and both are Fellows of the American College of Obstetrics and Gynecology (FACOG). In addition, both physicians are distinguished teaching members of the Clinical Faculty of their respective medical schools – The Baylor College of Medicine and The University of California. As practitioners, Dr. Jayne is the Medical Director of The Center for Women's Sexual Health at the Texas Medical Center and Dr. Wharton is the Chairman of the Department of Obstetrics and Gynecology and Site Director for Resident Education at Alta Bates Summit Hospital. As accredited, teaching and practicing physicians, Drs. Jayne and Wharton are persons of ordinary skill of the art who can construe terms such as implant and non-implant and understand the bounds of these terms when read in light of their usage in both the Guice patent and the present application. The facts that the Examiner claims are missing from their declarations are that these highly qualified, declarant experts in the human medical field intimately know the device of the present

application and have furthermore thoroughly studied the Guice patent in order to make valid comparisons. It is respectfully submitted that this is how any expert would base an opinion; nothing more is required. Furthermore, the declarations repeatedly refer to the "non-implanted" and "self-applied" language of Applicants' claim 1, so that these declarations refer specifically to features or limitations of Applicants' claim 1. It is respectfully submitted that Dr. Jayne and Dr. Wharton are qualified to, and do, address why the Guice patent would not be considered when developing a non-implanted, self-applied device as is required for the system defined in Applicants' claim 1. It is respectfully submitted that the Examiner is improperly substituting his opinion (i.e. conclusion – see MPEP 716.01(d)) in place of the opinions of these highly qualified experts.

With regard to claim 16 (see pages 5 and 11 of the Office Action), as indicated by the Examiner, Guice, in paragraph [0179], uses the "expandable" and "compressible" language, so that it is respectfully submitted that the use by Applicants in claim 16 of "non-expandable" and "non-compressible" directly addresses this feature of Guice. However, if desired by the Examiner, language such as "in cross-section" or "in diameter" could be added after each of the terms "non-expandable" and "non-compressible". At any rate, clearly Applicants' non-expandable and non-compressible probe unit of claim 16 is the opposite of Guice's expandable and compressible probe.

In view of the foregoing discussion, Applicants respectfully request reconsideration of the allowability of all of the pending claims. In addition, should the Examiner have any further comments or suggestions, the undersigned would very

much welcome a telephone call from him in order to resolve any outstanding issues and to expedite placement of the application into condition for allowance.

Respectfully submitted,

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Attachments